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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,664	04/09/2004	Martin Fuchs	C0989.70023US01	8791

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BOSTON, MA 02210-2206

EXAMINER
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SHAW, AMANDA MARIE

ART UNIT	PAPER NUMBER
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1634

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/821,664

Applicant(s)

FUCHS ET AL.

Examiner

Amanda M. Shaw

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11, 17, 23, 28, 30, 31, 36, 43 and 51 is/are pending in the application.
- 4a) Of the above claim(s) 11, 17, 28 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 23, 30-31, 36, and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 06/17/04, 11/22/04, 12/12/05, 11/24/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1-11, 17, 23, 28, 30-31, 36, 43, and 51 are currently pending. Applicant's election of Group I in the reply filed on October 26, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11, 17, 28, and 43 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim.

Accordingly, Claims 1-10, 23, 30-31, 36, and 51 have been examined herein.

### ***Information Disclosure Statement***

2. The information disclosure statements (IDS) submitted on 6/17/2004, 11/22/2004, 12/12/2005, and 11/24/2006 have been considered. References which have lines drawn through them have been considered but the line has been drawn through them because there is not a publication date for those references.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 9-10 are indefinite over the recitation of the phrase "wherein the second velocity gradient ends upstream of the detection zone by at least a distance equal to the polymer". This phrase is considered indefinite because it is unclear how a distance can be equal to a polymer.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Blankenstein (US Patent 6432630 Filed 1999).

As noted in the MPEP 211.02, "a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone." Further, in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999) the court held that if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, "then the preamble is of no significance to claim construction

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because it cannot be said to constitute or explain a claim limitation." In the present situation, the structural limitations of the apparatus are able to stand-alone and the preamble limitation is not accorded patentable weight. Accordingly, the phrase "An apparatus for positioning a polymer in a micro channel" merely sets forth the intended use of the claimed structure, but does not limit the scope of the claims.

Regarding Claims 1-10 Blankenstein teaches an apparatus comprising: (i) a flow channel having a first inlet positioned at one end of the flow channel for entering the fluid into the flow channel, a first outlet means positioned at the other end of the flow channel for discharging the fluid from the flow channel, and side walls; (ii) a first section of the flow channel that has a first velocity gradient; (iii) second and third inlet means for entering a first and second guiding buffer into the flow channel (herein interpreted as opposed flow control channels); a flow controller to control the flow velocities of the guiding buffers and the flow within the flow channel; a second section of the flow channel disposed between the second inlet and the second end of the micro channel, which has a second velocity gradient; and a detection zone (See Fig 1, Columns 2-6). Further Blankenstein teach that the flow through the flow channel can have a laminar flow, and that the stream of particles (i.e. DNA or RNA) can be positioned as desired within the flow channel by controlling the flow velocities of the fluid containing particles at the particle inlet of the member and flow velocities of guiding buffers at corresponding inlets. (Column 4). Additionally when the flow is laminar the two fluids flow through the flow channel in parallel abutting each other hence creating a fluidic boundary (Column 5). Blankenstein also teach that the velocities of each fluid can be controlled using

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either 2 way or 3 way control valves which are controlled by pressure (Column 15).

Further Blankenstein teach an apparatus wherein the substantially opposed sidewalls are substantially non-parallel. For example Figure 1 demonstrates that the opposed sidewalls are curved.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30, 36, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blankenstein (US Patent 6432630 Filed 1999) in view of Chan et al (US Patent 6762059 Filed 2001).

As noted in the MPEP 211.02, "a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone." Further, in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999) the court held that if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, "then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." In the present

situation, the structural limitations of the apparatus are able to stand-alone and the preamble limitation is not accorded patentable weight. Accordingly, the phrases "An apparatus for maintaining a polymer in an elongated configuration", "An apparatus for detecting a polymer", and "An apparatus for holding a polymer on a microchip" merely set forth the intended use of the claimed structure, but do not limit the scope of the claims.

The teachings of Blankenstein are presented above in paragraph 4.

Regarding Claim 30 Blankenstein does not teach an apparatus which comprises a micro channel having opposed sidewalls defining a first micro channel width, a second micro channel width, smaller than the first width, and a transition between the first and second micro channel widths; wherein the transition adapted to contact and inhibit relaxation of an elongated polymer contained within the first micro channel width.

However Chan et al teach an apparatus for the characterization of polymers which comprises a first and second end and sidewalls. Specifically Chan et al teach that sidewalls which are funnel shaped can aid in the elongation of a polymer. Thus Chan et al teach a micro channel that has a first width, a second width that is smaller than the first and a transition between the first and second widths. Further Chan et al teach that funnel shaped channels apply elongation forces in a regular and continuous manner so that as the polymer flows down the channel it experiences increasing elongation forces which counteract the tendency for the polymer to recoil thus keeping it elongated (Column 30-31). Thus the channel is adapted to contact and inhibit relaxation of an elongated polymer contained within the first micro channel width.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Blankenstein by using a flow channel comprising sidewalls that are funnel shaped as suggested by Chan et al because an apparatus which comprises funnel shaped side walls can be used to elongate a polymer as it is traveling through the channel. This would be especially beneficial to practitioners in the art who are interested in elongating polymers in order to further study the internal structure of the polymer. Typically polymers are in a coiled conformation however when a polymer flows through a funnel shaped channel, the shape of the channel applies elongation forces in a regular and continuous manner so that as the polymer flows down the channel it experiences increasing elongation forces which counteract the tendency for the polymer to recoil thus keeping it elongated. Thus the elongate polymers can be further studied.

Regarding Claim 36 Blankenstein does not teach an apparatus which comprises an obstacle field arranged between the first and second ends at the micro channel.

However Chan et al teach an apparatus for the characterization of polymers which comprises an obstacle field arranged between the first and second ends at the micro channel. Specifically Chan et al teach that when a polymer molecule in a fluid flow encounters an obstacle of appropriate dimension, it may hook around the obstacle such that portions of the polymer chain on each side of the obstacle become elongated (Columns 28 and 33-34). When this occurs in the detection zone, the elongated polymer can be detected.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Blankenstein by using a flow channel comprising obstacle fields as suggested by Chan et al because an apparatus which comprises obstacle fields can be used to elongate a polymer as it is traveling through the channel. This would be especially beneficial to practitioners in the art who are interested in elongating polymers in order to further study the internal structure of the polymer. Typically polymers are in a coiled conformation however when a polymer flows through a channel and encounters an obstacle of appropriate dimension, it may hook around the obstacle such that portions of the polymer chain on each side of the obstacle become elongated (Columns 28 and 33-34). Thus the obstacles aid in keeping the polymer elongated so that it can further be studied.

Regarding Claim 51 Blankenstein does not teach an apparatus which comprises a micro channel disposed on a microchip wherein the micro channel is arranged on the microchip with a first bend causing a first portion of the micro channel to be located adjacent to and aligned with a second portion of the micro channel.

However Chan et al teach an apparatus which comprises a micro channel disposed on a microchip. Further Chan et al teach that the channels can be zigzagged. Specifically Chan et al teach that the benefit of using zigzagged channels is that they create multiple detection possibilities. For instance when a detector is arranged in a channel the channel can be aligned so that it repeatedly crosses the detection zone at defined locations. Thus the polymer being studied can be observed several times (Column 33).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Blankenstein by using a zigzagged shape flow channel on a microchip as suggested by Chan et al because an apparatus which comprises a zigzag shape flow channel can be used to observe the polymer being detected several times. Further the benefit of being on a chip is that the chip is portable, cheap, and analysis is easy to perform.

6. Claims 23 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blankenstein (US Patent 6432630 Filed 1999) in view of Chan et al (US Patent 6762059 Filed 2001) and in further view of Perkins (Science 1997).

As noted in the MPEP 211.02, "a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone." Further, in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999) the court held that if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, "then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." In the present situation, the structural limitations of the apparatus are able to stand-alone and the preamble limitation is not accorded patentable weight. Accordingly, the phrases "An

apparatus for elongating a polymer" and "An apparatus for elongating a polymer and maintaining it in an aligned or elongated configuration" merely set forth the intended use of the claimed structure, but do not limit the scope of the claims.

The teachings of Blankenstein and Chan et al are presented above in paragraphs 4 and 5.

Regarding Claim 23 the combined references do not teach not teach an apparatus which further comprises a polymer elongation zone with first and second end flow controllers which direct fluid through the micro channel from the first and second ends towards the polymer elongation zone.

However Perkins et al teach an apparatus for the characterization of polymers in which fluid flows from both ends of the channel toward the polymer elongation zone (See Figure 2A inset). The flow demonstrated here produces a stagnation point in the micro channel which is beneficial for prolonged observation of the polymer or manipulation of the polymer.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Blankenstein by using a flow channel in which fluid flows from both ends of the channel toward the polymer elongation zone as suggested by Perkins et al because an apparatus which comprises a flow channel in which fluid flows from both ends of the channel toward the polymer elongation zone produces a stagnation point in the micro channel. This would be especially beneficial to practioners in the art who are interested in studying the internal

structure of the polymer. The stagnation point allows for prolonged observation of the polymer or manipulation of the polymer.

Regarding Claim 31 Blankenstein do not teach an apparatus wherein one of the flow channels has at least one bend. Blankenstein further do not teach an apparatus which further comprises a polymer elongation zone with first and second end flow controllers which direct fluid through the micro channel from the first and second ends towards the polymer elongation zone.

However Chan et al teach an apparatus wherein one of the flow channels has at least one serpentine bend. A micro channel comprising a bend helps achieve stretching because as the fluid encounters changes in its path the fluid on the outside of the curve or corner will take longer to go around the turn than the fluid on the inside of the curve or corner. This so called "racetrack effect" can help stretch out polymers (Column 32).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Blankenstein by using a flow channel which comprises at least one bend as suggested by Chan et al because an apparatus which comprises a bend helps achieve stretching because as the fluid encounters changes in its path the fluid on the outside of the curve or corner will take longer to go around the turn than the fluid on the inside of the curve or corner. This so called "racetrack effect" can help stretch out polymers (Column 32). This would be especially beneficial to practitioners in the art who are interested in elongating polymers in order to further study the internal structure of the polymer. Typically polymers are in

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a coiled conformation however when a polymer flows through a channel and encounters a bend it causes the polymer to become elongated (Columns 28 and 33-34). Thus the bends aid in keeping the polymer elongated so that it can further be studied.

However Perkins et al teach an apparatus for the characterization of polymers in which fluid flows from both ends of the channel toward the polymer elongation zone (See Figure 2A inset). The flow demonstrated here produces a stagnation point in the micro channel which is beneficial for prolonged observation of the polymer or manipulation of the polymer.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Blankenstein by using a flow channel in which fluid flows from both ends of the channel toward the polymer elongation zone as suggested by Perkins et al because an apparatus which comprises a flow channel in which fluid flows from both ends of the channel toward the polymer elongation zone produces a stagnation point in the micro channel. This would be especially beneficial to practitioners in the art who are interested in studying the internal structure of the polymer. The stagnation point allows for prolonged observation of the polymer or manipulation of the polymer.

### ***Conclusion***

7. No Claims are allowed.

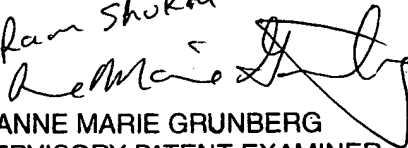
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571)

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272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw  
Examiner  
Art Unit 1634

for Ram Shukla  
  
ANNE MARIE GRUNBERG  
SUPERVISORY PATENT EXAMINER